

App. No. 10/736,266  
Filed December 15, 2003  
Amendment dated January 13, 2006 in response to non-final Office Action of October 21, 2005  
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### **AMENDMENTS TO THE CLAIMS**

Please amend claims 21 and 23 as indicated in the Listing of Claims below, which replaces all prior versions of claims in the application.

### **LISTING OF CLAIMS**

1. (original) A tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea, said valve unit comprising:
  - (a) a first end adapted for connection to the free end of the tracheotomy tube;
  - (b) a second end comprising a valve unit inlet;
  - (c) a first valve that permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales, and blocks airflow from the tube through the valve unit when the patient exhales; and
  - (d) a second valve that permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water.
2. (original) The valve unit of claim 1 comprising a seating ring and a thin, flexible diaphragm biased against the seating ring, thereby making positive closure contact therewith.
3. (original) The valve unit of claim 2 wherein the diaphragm is made of silicone sheet material.
4. (original) The valve unit of claim 2 wherein the diaphragm is biased against the seating ring by a pressure of from about 8 to about 15 mm of water head.

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5. (original) The valve unit of claim 2 comprising a rivet for connecting the diaphragm to the seating ring, the rivet having a length to bias the diaphragm against the seating ring.
6. (original) The valve unit of claim 5 wherein the rivet has an axial bore hole through it and comprises the second valve.
7. (original) The valve unit of claim 6 wherein the second valve comprises a slit valve or an umbrella valve.
8. (original) The valve unit of claim 7 wherein the diaphragm is biased against the seating ring by a pressure of from about 8 to about 15 mm of water head.
9. (original) The valve unit of claim 8 wherein the diaphragm is made of low-modulus silicone sheet material.
10. (original) The valve unit of claim 9 wherein the second valve permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.
11. (original) The valve unit of claim 1 wherein the second valve permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.
12. (original) The valve unit of claim 11 wherein the second valve comprises a slit valve or an umbrella valve.

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13. (original) The valve unit of claim 12 comprising a seating ring and a thin, flexible diaphragm biased against the seating ring, thereby making positive closure contact therewith.
14. (original) The valve unit of claim 13 comprising a rivet for connecting the diaphragm to the seating ring, the rivet having a length to bias the diaphragm against the seating ring.
15. (original) The valve unit of claim 14 wherein the second valve is located in the rivet.
16. (original) The valve unit of claim 1 wherein the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is about 4 cm of water, and is fully open when the intrathoracic pressure during expiration is about 10 cm of water.
17. (original) The valve unit of claim 16 wherein the second valve comprises a slit valve or an umbrella valve.
18. (original) The valve unit of claim 17 comprising a seating ring and a thin, flexible diaphragm biased against the seating ring, thereby making positive closure contact therewith.
19. (original) The valve unit of claim 18 comprising a rivet for connecting the diaphragm to the seating ring, and the rivet having a length to bias the diaphragm against the seating ring.
20. (original) The valve unit of claim 19 wherein the second valve is located in the rivet.

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21. (currently amended) A tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea, said valve unit comprising:
  - (a) a first end adapted for connection to the free end of the tracheotomy tube;
  - (b) a second end comprising a valve unit inlet;
  - (c) a first valve that permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales, and blocks airflow from the tube through the valve unit when the patient exhales, said first valve comprising a seating ring, a thin, flexible diaphragm biased against the seating ring, thereby making positive closure contact therewith, and a rivet for connecting the diaphragm to the seating ring, the rivet having a length to bias the diaphragm against the seating ring; and
  - (d) a second valve that begins to open to permit[[s]] airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 3 cm of water, is fully open when the intrathoracic pressure reaches about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water, wherein the second valve comprises a slit valve or an umbrella valve that is located in an axial bore hole of the rivet.
22. (original) The valve unit of claim 21 wherein the diaphragm is made of low-modulus silicone sheet material.
23. (currently amended) The valve unit of claim 22 wherein the second valve begins to open to permit[[s]] airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 4 cm of water, is fully open when the intrathoracic pressure reaches about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.

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24. (original) The valve unit of claim 22 wherein the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is about 4 cm of water, and is fully open when the intrathoracic pressure during expiration is about 10 cm of water.
25. (original) The valve unit of claim 24 wherein the second valve allows increasing airflow through it as the intrathoracic pressure during expiration increases beyond 4 cm of water until maximum airflow is achieved at a pressure of about 10 cm of water.